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NGUYEN, BAO THUY L.				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/563,659

Applicant(s)

SCHWIND ET AL.

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment submitted June 26, 2008 has been received. Claim 2 has been canceled.

Claims 1, 3-19 are pending. Claims 10-19 has been withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites a device comprising "a membrane" with "an application point", a group of "at least two indicator zones", at least one absorption region where the flow directions (of liquid sample) from the application zone through the indicator zones toward the absorption region are parallel and at least two flow tracks are present. However, neither the specification nor claim 1 properly describes how *two parallel* flow tracks can be present on *one* membrane. In order for two flow tracks to be present on the same membrane, there must be some sort of divider or barrier separating them, but neither the claims nor the specification discloses such a feature.

Therefore, claims 1-9 lack proper written description to reasonably convey to one skilled in the art at the time the applicant was filed that applicant had possession of the claimed invention.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-9 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because it is unclear how two different flow tracks can be present on only one membrane without any divider or barrier separating them.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by May (WO 88/08534).

May teaches a device comprising a hollow casing constructed of moisture-imperious solid material containing a dry porous carrier which communicates directly or indirectly with the exterior of the casing such that a liquid test sample can be applied to the porous carrier, the

device contains labeled specific binding reagents for an analyte, and unlabeled specific binding reagent for the same analyte which unlabeled reagent is permanently immobilized in a detection zone on the carrier material (page 3). May teaches a plurality of detection zones arranged in series or in parallel on the porous solid phase material through which the aqueous liquid sample can pass progressively, can also be used to provide a quantitative measurement of the analyte or can be loaded individually with different specific binding agents to provide a multi-analyte test (page 12). May also teaches an absorbent sink provided at the distal end of the carrier material to aid in the flow of sample and to ensure that excess labeled reagent from the first zone which does not participate in any binding reaction in the second zone is flushed away from the detection zone (page 11, lines 1-17).

With respect to the recitation of different, parallel flow tracks, May discloses test strips arranged in parallel such that one application of fluid sample initiate simultaneous flow in the elements enabling the detection of different analytes. See page 12, lines 7-20.

With respect to claim 2, the indicator zones are arranged on separate but parallel test strips, therefore, the test liquid for any one flow track flow through only one indicator zone.

With respect to claim 3, May teaches indicator zones arranged in linear rows. See page 35, lines 28-36.

With respect to claim 4, May teaches antibodies conjugated to gold sol labels for use in the indicator zone. See page 35, lines 30-32.

With respect to claim 5, May teaches the use of antibodies and antibody fragments.

With respect to claim 6, May teaches the use of nitrocellulose membrane. See page 5, line 11.

With respect to claim 7, May teaches a nitrocellulose sheet sandwiched between two supporting plastic sealing sheet. See page 14, lines 5-7.

With respect to claim 8, May teaches backing the membrane to increase handling strength. See page 13, lines 33-36.

With respect to claim 9, May teaches a housing containing the membrane. See page 7.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hardman (US 7,303,923) in view of May (WO 88/08534).

Hardman discloses a device comprising a porous material, one or more test reagents on the porous material and a transparent water-impermeable coating polymer attached to the porous material so as to define a continuous bibulous compartment. See column 1, lines 39-48. With respect to a device having one application zone, Hardman discloses that there is only one entrance to the bibulous compartment. See column 2, lines 26-27. With respect to a device having at least two indicator zones, Hardman discloses more than one detection reagents may be present to detect a plurality of analytes. See column 4, lines 45-56. With respect to a device having different, parallel flow tracks, Hardman discloses a bibulous compartment comprising a central body with a plurality of channels connected thereto. Detection reagents are provided in each channel. See column 4, line 57 through column 5, line 3, and figures 2 and 3.

Hardman differs from the instant invention in failing to teach at least one absorption region which takes up the liquid after having passed the indicator zones.

May discloses a device as discussed above. May teaches an absorbent sink provided at the distal end of a carrier material. The sink can be an additional absorbent paper or a length of the porous solid phase material which extends beyond the detection zone. See page 11, lines 11-17.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the absorbent sink as taught by May in the device of Hardman because such a feature provides the advantage of the ability to flush away excess fluid from the detection zone thereby preventing back flow and contamination of the detection zone.

With respect to claim 2, Hardman discloses that the channels are separated by liquid impervious polymers and that the reagents are provided in the channel. Therefore, the test liquid

in the different flow tracks does not flow through more than one indicator zones. See column 9, lines 17-22.

With respect to claim 3, May discloses linear rows of indicator zones.

With respect to claims 4 and 5, both Hardman and May discloses the use of antibodies and their fragments.

With respect to claim 6, both Hardman and May teaches the use of nitrocellulose membrane.

With respect to claim 7, May and Hardman teaches sealing the membrane with various polymers. See Hardman, column 8, lines 46-64.

With respect to claim 8, May teaches backing the membrane to increase handling strength.

With respect to claim 9, Hardman and May both teaches placing the membrane inside a casing or protective covering. See Hardman, column 2, lines 35-46.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-9 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-3, 7, 11-12 and 14-15 of copending Application No. 10/563,681. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

Both sets of claims are directed to a device comprising a membrane, an application zone, at least one group of at least two indicator zones, at least one absorption region and the flow directions from the application zone through the indicator zones are substantially parallel and at least two different flow tracks are present.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Response to Arguments

11. Applicant's arguments filed 26 June 2008 have been fully considered but they are not persuasive.

Applicant argues that the claims are fully supported and described by the specification and cite page 6, lines 1-5 and claim 2 as evidence.

This argument is not persuasive. Claim 1 recites a membrane having an application point, indicator zones and an absorption region. The device is recited as having "flow directions" from the application point pass the indicator zone to the absorption region, and that these "flow directions" are parallel. The device is also recited as having at least two different flow tracks where the indicator zones are positioned and arranged such that liquid sample for one flow track does not flow through more than one indicator zone. This device is not supported by specification as originally filed, and support for this device is not found at page 6, line 1-5 nor in claim 2 as asserted by Applicant. First, what are the *flow directions*? Are they the same or different? i.e. are the *directions* all go from the sample application zone through the indicator zones toward the absorbent zone? Second, how does the device have *two flow tracks* when the device is composed of *a* membrane with no dividers or separators to define the flow tracks. Third, how can these *flow directions* be parallel when no dividers or separators are available to define the flow tracks? And last, how can the arrangement of the indicator zones affect the flow tracks? The specification at page 6, lines 1-5 recites that "...*the indicator zones are so arranged that the sample liquid for each flow track will flow through not more than one indicator zone. For example, the indicator zones are provided on the membrane in staggered relationship. This arrangement of the indicator zone is, in this context, preferably configured in a row extending diagonally from proximal to distal or vice versa.*" Nothing here provide adequate description for a device comprising **a membrane having at least two different flow tracks resulting from flow directions that are substantially parallel.**

The arguments with respect to the 112, second paragraph rejection is also not persuasive for the reasons stated above.

The argument with respect to the rejection of claims 1-9 as being anticipated by May is not persuasive. Applicant argues that May does not teach a membrane with at least two different flow tracks. Although May does not specifically recites that its membrane has at least two different flow tracks, May teaches a device that is made of the same materials with those of the instant invention, nitrocellulose, therefore, it is inherent in the device of May that more than one flow tracks are present and the flow would be substantially parallel from the sample application point to the absorbent. There is no structural features recited in the instant claims that define the different flow tracks and since the device of May is made of the same materials as those of the instant claims, these two devices would be expected to have the same inherent characteristics and function.

The argument that the Hardman device requires separate membranes and physical barrier to separate the channels in a prerequisite for simultaneous detection of a plurality of analytes and that this is different from the instant claims where the device comprise a single membrane with multiple flow tracks that are substantially parallel is not persuasive.

Hardman specifically teaches a device having a **porous substrate** that is divided into channels by a doping polymer. Nowhere in the device of Hardman is there a recitation that the device requires multiple membranes. Only that the one membrane is divided into multiple channels.

The argument that the flow in the device of Hardman is not parallel but is in a Y-shaped is not persuasive. Hardman teaches that the sample flows from the sample application point to

the multiple indicator zones, and since the indicator zones are in parallel channels, the flow is obvious parallel. Furthermore, figure 3, at least, clearly shows parallel channels.

The response regarding the ODP rejections is acknowledged. These rejections will be held in abeyance.

Conclusion

12. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao-Thuy L. Nguyen/
Primary Examiner, Art Unit 1641
17 September 2008